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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,122	08/22/2003	Nagi M. Awad	119.002	8854

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EXAMINER

ZIMMER, MARC S

ART UNIT	PAPER NUMBER
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1712

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/646,122

Applicant(s)

AWAD, NAGI M.

Examiner

Marc S. Zimmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-15 and 17-37 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Priority

Applicant is advised that they are not entitled to the benefit of the priority date of the provisional application as the claims are not fully supported by that disclosure. For instance, while the provisional application discloses specific examples of components (A) and (B) that adhere to the structural description of these components, said specific examples do not enable the full molecular weight ranges and, hence the full range(s) for the number of repeat units of either component. Also, the provisional application only contemplates vinyl group-substituted polydimethylsiloxane or diphenyldimethylpolysiloxane whereas component (A) of the instantly claimed invention also contains mention of those polymers bearing ethyl and propyl substituents as well as terminal groups other than vinyl. Similar remarks can be made concerning the lack of enablement of all permutations of component (B) of the claimed invention. Although, there are numerous other claimed aspects that the provisional application fails to fully support, a comprehensive outline of the provisional application's deficiencies will not be provided herein for brevity. Each of the independent claims recites the same limitations with respect to components (A) and (B). Thus, it can be stated that none of the claims are fully enabled by the provisional application. This is important because Applicant admits sales activity of products made by a process consistent with that presently claimed more than one year prior to the filing date of the present application.

As an aside, Applicant purports that Formulations C and O, which they acknowledge were offered for sale more than one year prior to the filing date of the present application, have "an effective filing date" that is the same as the filing date of

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the provisional application ostensibly because they were first described in a printed publication on that date. However, this information would not appear to be material to an on-sale bar. For the purposes of making a rejection under 35 U.S.C. 102(b) using the rationale that revealed commercial activity represents an on-sale bar, the so-called effective date is that where the product was first offered for sale.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-15 and 17-33 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention. The Examiner's entire rationale for this rejection was originally articulated in the Office correspondence dated July 27 and remains largely the same except that the Examiner's initial contention was that at least formulations C and O had been made available for sale more than one year prior to the effective filing date. It is now appreciated that, in fact, the sales activity had been less than one year before the provisional application but Applicant cannot claim the benefit of said provisional application for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-6, 23, 28, and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuwata et al., U.S. patent # 4,987,169.

Claims 2, 3, 19-27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuwata et al., U.S. patent # 4,987,169 in view of the dictionary definition of "mill" taken from Merriam-Webster's Dictionary.

It is noted for the record that all of claims 1-6, 19-29, and 33-37 take the form of product-by-process claims. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process" *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

"The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974).

Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

The fact that these claims are product-by-process claims is significant because, while Applicant has implicitly suggested that the claimed gels are different from those of the prior art (Applicant states in paragraph 10 that an objective of their invention is to prepare high viscosity, clear silicone gels and paragraph 9 implies that this goal has not yet been realized), they have not substantiated that the claimed gels are different from those of the prior art by the presentation of empirical evidence. Indeed, Applicant has provided no comparative examples of similarly constituted gels that, although they were prepared from similar starting materials, were nonetheless inferior in their clarity. This is important because, in the absence of any empirical data, the Examiner cannot conclude with any certainty that the processes (i) where polymerization is initially carried out with mixing, and said mixing is halted when gelling is observed or (ii) wherein the polymerization reaction is carried out in a manner in which a substantial portion of the reaction mass is not subject to substantial shearing forces do, in fact, provide a different product as evidenced by its different properties. For this reason, the rejections over Kuwata et al. are hereby maintained. The relevant teachings and their locations in the reference were provided in the correspondence dated July 27.

Applicant is encouraged to submit a 132 Declaration containing carefully devised experiments that clearly illustrate the formation of different products when formation of a gel entails exposure to shear throughout the polymerization (as would appear to be the case in Kuwata's invention) versus the instant cases where mixing is stopped at the point that gelation is witnessed or a substantial portion of the reaction mass is not

subject to substantial shearing forces during polymerization. In doing so, Applicant should avoid comparative processes where more than one variable is different for the obvious reason that it would be impossible to ascertain which variable was responsible for any differences in the product obtained. Of course, a properly executed declaration would serve only to obviate the 35 U.S.C. 103 rejections as it does not represent a means of overcoming an on-sale bar.

Allowable Subject Matter

Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Although it is quite possible that the method employed to prepare Formulations C and O also included the limitations of claim 16, this cannot be confirmed as Applicant's description of on-sale activity does not expressly mention a formulation made using this approach.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc S. Zimmer whose telephone number is 571-272-1096. The examiner can normally be reached on Monday-Friday 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on 571-272-1302. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 17, 2004


MARGARET G. MOORE
PRIMARY EXAMINER